IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. Serial No.: 09/955,639 Group Art Unit: 1780

Filing Date: 09/19/2001 Examiner: Celsa, Bennett

Applicants: Niles et al. Attorney Docket No.: 34506.115

Title: Tryptase Substrates and Assay for Tryptase Activities Using Same

RESTRICTION & ELECTION OF SPECIES RESPONSE

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To the Commissioner:

Responsive to the Restriction and Election of Species Requirements dated April 28, 2003, the time period for response thereto being set to expire June 28, 2003, by virtue of the Petition for One-Month Extension of Time filed herewith, Applicants provisionally elect, **with traverse**, Group II, Claims 4-15, 28-37, 41, 42, and 44-47. Responsive to the election of species requirement, Applicants elect, **with traverse**, the peptide PRNK (SEQ. ID. NO: 2). Claims 4-10, 28-37, 41, 42, and 44-47 read thereon.

REMARKS

Applicants provisionally elect, **with traverse**, Group II, Claims 4-15, 28-37, 41, 42, and 44-47. Applicants traverse the requirement because restriction is proper only if the claims of the restricted groups are independent or patentably distinct (MPEP §803). Applicants respectfully traverse the Restriction Requirement on the grounds that the Office has not carried the burden of providing any reason and/or example to

support the conclusion that the claims of the restricted groups are patentably distinct.

Specifically, in forwarding the restriction between the claims of Groups I, II, and III, the Office states:

> Inventions I-III are drawn to different peptides, compositions and the use thereof, in which the peptides of the different groups are distinct due to differences in chemical structure, properties and are capable of separate manufacture and/or use and which require different and separately burdensome manual/computer sequence, structure and bibliographic searches."

Applicants submit that this statement is insufficient to support a restriction requirement between any of the claims of Groups I, II, and III because the statement is wholly conclusory. The restriction requirement does not explain why any of these considerations renders the claims patentably distinct. MPEP §803 requires the Office to advance substantive reasons for finding claims to be patentably distinct. It is insufficient merely to identify mutually exclusive claims, as has been done in the present Office Action. Rather, the MPEP requires some reason, based on either fact or theory, to support the position that the claims recite patentably distinct inventions.

Because the Office has not supported the restriction requirement by way of reasons or examples, Applicants submit that the restriction requirement between Groups I, II, and III is improper and should be withdrawn.

Regarding Groups I and II/III, the Office has characterized the relationship between Groups I and II/III as product and process of use. Citing MPEP §806.05(h), the Examiner states that claims in this relationship can be shown to be distinct if either of the following can be shown: (1) that process **as claimed** can be practiced with another materially different product; or (2) that the product as claimed can be used in a materially different process. The Examiner goes on to state that, in the present application, the peptides recited in the claims can be used as pharmaceutically-active agents. Applicant submits that the reason offered by the Examiner is insufficient to support a conclusion of patentable distinctness between the restricted claims. The

Examiner has provided no indication as to the means for, or the feasibility of, using the claimed peptides as pharmaceuticals.

Accordingly, because the Office has not carried the burden of providing technologically sound reasons or examples for concluding that the claims of the restricted groups are patentably distinct, the restriction requirement is improper and should be withdrawn.

Moreover, Applicants note that the MPEP also states that "If the searching and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct invention." (MPEP §803, emphasis added.) Applicants respectfully point out that all of the claims recite isolated polypeptides comprising a defined order of residues, namely P4-P3-P2-P1. This is a very small, well-defined class of polypeptides. In fact, the Manual of Classification includes a specific class/sub-class designation addressing small peptides: Class 530, subclass 300 is defined as peptides of 3 to 100 amino acid residues. Moreover, paragraph (3) of that sub-class definition states:

> (3) Note. Related peptides. A peptide is classifiable in a given subclass if its structure corresponds to at least half the amino acid residues of the named peptide. The product of side chain substitution, *C or N terminal chain will be classified with the named peptide as related peptides. The product of a replacement reaction will be classified as a related peptide so long as less than half the amino acid residues of the named peptide have been replaced. The product of a removal reaction or a partial sequence (i.e., fragments) will be classifed as a related peptide if half the amino acid residues of the named peptide are present.* Polypeptides which are formed by joining the named peptide of identical sequence to the named peptide should be originally classified on the basis of the named peptide and cross-referenced to the appropriate subclasses. (emphasis added).

Applicants therefore submit that a search of Class 530, subclass 300 will encompass all of the now-pending claims. Because this is the case, there is no additional burden on the Office if the restriction requirement is no made and the entire claim set is searched in the present application. In short, the search for the entire claim set is coextensive because all three groups recite the same

sequences. Therefore, no serious burden is placed on the Office in examining the entire claim set.

Applicants therefore submit that the rejection between the claims of Groups I, II, and III is improper and should be withdrawn.

ELECTION OF SPECIES

Applicants traverse the election of species requirement because the Office has made no attempt to show, by way of reasons or examples, how the species identified by the Examiner are patentably distinct. In the same fashion as a restriction requirement, the MPEP requires that the Office advance some objective reasoning as to why the identified species are patentably distinct. This has not been done in the present Office Action. The Office has simply identified multiple sequences and concluded, without any supporting commentary, that the sequences are patentably distinct. Applicants therefore traverse the election of species requirement because the mere identification of multiple sequences is not sufficient to support an election of species requirement.

Further, applicants point out that sequences 1-21 identified in the instant application as synthetic polypeptides all have the formula P4-P3-P2-P1 and that a search of one sequence should be coextensive with the other sequence. Therefore, a search of all the sequences identified in the application should not place an undue burden on the Office.

Applicants further note that, with the provisional election of a single species, should no prior art be found that anticipates or renders obvious the elected species, the search of the claims will be extended to the other, non-elected species. MPEP §803.02.

CONCLUSION

Applicants submit that the application is now ready for examination on the merits. Early notification of such action is earnestly solicited.

Respectfully submitted,

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